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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/774,751	02/09/2004	Jerry R. Grychowski	6298-449	6148

757 7590 08/09/2006

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EXAMINER
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PATEL, NIHIR B

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/774,751	Applicant(s) GRYCHOWSKI ET AL.	
	Examiner Nihir Patel	Art Unit 3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06.18.2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-14 and 24-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-14 is/are allowed.
- 6) ☒ Claim(s) 1, 3-10 and 24-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Amendment*

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. The examiner agrees with the applicant's arguments that claims 5 and 31 were not addressed and the use of a new reference on original claims 24-27 was improper in a final rejection. Therefore, the finality of the action dating February 8<sup>th</sup>, 2006 is withdrawn.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

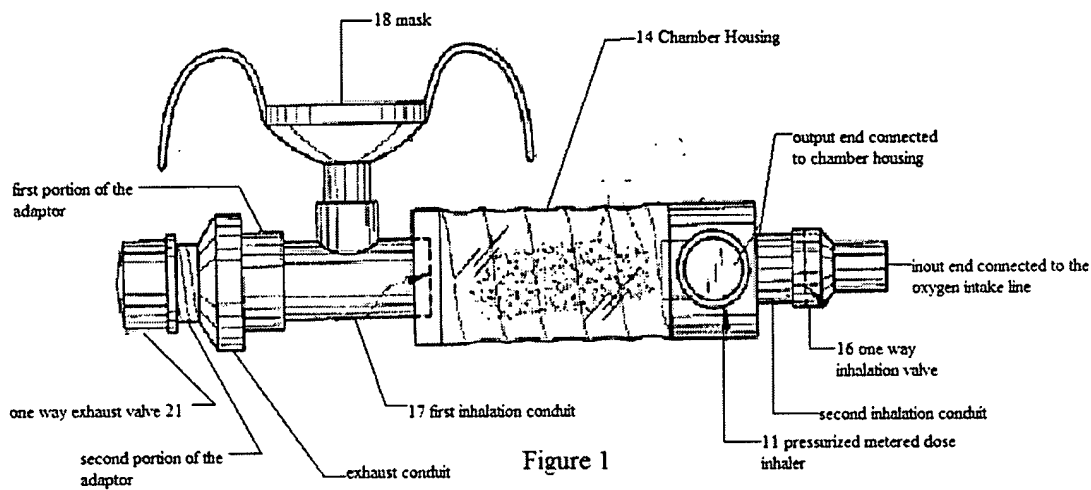
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims **1, 3, 4, 9, 10, 29 and 30** are rejected under 35 U.S.C. 102(b) as being anticipated by Farmer (US 2002/0069870).

4. As to **claim 1**, Farmer discloses an apparatus that comprises a chamber housing **14** (see **figure 1**) defining an interior space and comprising an input end and an output end (see **figure 1**); a one way inhalation valve **16** (see **figure 1**) positioned upstream of the interior space, the one way inhalation valve operative to permit a flow of gases into the interior space of the chamber housing (see **figure 1 and page 2 paragraph [0022]**); a first inhalation conduit **17** (see **figure 1 and page 2 paragraph [0022]**) communicating with the output end of the chamber, the inhalation conduit adapted to transmit medication to the patient; a second inhalation conduit (see **figure 1; the portion located next to the one way valve 16**) communicating with the input end

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of the chamber housing wherein the one way inhalation valve is located in the second inhalation conduit , the second inhalation conduit comprising an oxygen intake line communicating with the one way valve inhalation valve; an exhaust conduit (see **figure 1**; the portion located just before the exhaust valve 21) communicating with the first inhalation conduit 17; and a one way exhaust valve 21 (see **figure 1**) located in the exhaust conduit, the one way exhaust valve adapted to prevent a backflow of gas from the exhaust conduit into the first inhalation conduit.



5. **As to claim 3**, Farmer teaches an apparatus that further comprises pressurized metered dose inhaler **11** in flow communication with the chamber housing downstream of the inhalation valve (**see figure 1**).
6. **As to claim 4**, Farmer teaches an apparatus wherein the second inhalation conduit comprises an adaptor having an output end connected to the input end of the chamber housing and input end connected to the oxygen intake line, the adapter having the one way valve disposed therein (**see figure 1**).
7. **As to claim 9**, Farmer teaches an apparatus wherein the first inhalation conduit comprises a mask **18** (**see figure 1**).
8. **As to claim 10**, Farmer teaches an apparatus comprising an adaptor connected to the output end of the chamber housing and comprising a first portion defining at least a portion of the first inhalation conduit and a second portion defining at least a portion of the exhaust conduit, wherein the one way exhaust valve is positioned in the second portion of the adaptor, and further comprising an exhaust line connected to the second portion and defining at least a portion of the exhaust conduit (**see figure 1**).
9. **As to claim 29**, Farmer teaches an apparatus wherein the second inhalation conduit is isolated from and does not communicate with ambient air (**see figure 1**).
10. **As to claim 30**, Farmer teaches an apparatus wherein the oxygen intake line and the exhaust conduit are connected to a ventilator (**see figure 1 and paragraph [0004]**).

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. **Claims 24-27 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer (US 20020069870).**

14. **As to claim 24**, Farmer teaches a method step comprising the step transmitting oxygen from a gas source through a holding chamber and an inhalation conduit to the patient during an inhalation sequence of a breathing cycle (**see figure 1**); introducing the medication into the holding chamber **14** (**see figure 1**); preventing a substantial transmission of an exhaust gas into the holding chamber during an exhalation sequence of the breathing cycle (**see figure 1**); transmitting a substantial portion of the exhaust gas into an exhaust conduit during the exhalation sequence (**see figure 1**); and preventing a substantial transmission of the exhaust gas from the

exhaust conduit into the inhalation conduit during subsequent inhalation sequences of subsequent breathing cycles (see figure 1).

The claimed method steps would have been obvious because they would have resulted from the use of the device of Farmer.

15. **As to claim 25**, Farmer teaches a method step wherein preventing the substantial transmission of the exhaust gas into the holding chamber during the exhalation sequence comprises creating a back pressure in the holding chamber (see figure 1).

16. **As to claim 26**, Farmer teaches a method step of creating the back pressure in the holding chamber comprises providing a one way valve between the gas source and the holding chamber, and preventing the flow of the exhaust gas from the holding chamber toward the gas source with the one way valve (see figure 1).

17. **As to claim 27**, Farmer teaches a method step of preventing a substantial transmission of the exhaust gas from the exhaust conduit into the inhalation conduit during subsequent inhalation sequences comprises providing a one way valve in the exhaust conduit, and preventing the flow of the exhaust gas from the exhaust conduit to the inhalation conduit with the one way valve (see figure 1).

18. **As to claim 31**, Farmer teaches a method step of transmitting oxygen from a gas source comprises transmitting the oxygen from a ventilator during the inhalation sequence and further transmitting the substantial portion of the exhaust gas from the exhaust to the ventilator during the exhalation sequence (see paragraph [0004]; the reference refers to a ventilator breathing circuit which can be defined as a portion of the exhaust gas from the exhaust gas conduit returning to the ventilator during the exhalation sequence).

19. **Claims 5, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer (US 20020069870) in view of Mantz (Us 6,527,011).**

20. **As to claim 5**, Farmer discloses the applicant's invention as claimed with the exception of providing an inhalation valve that comprises a valve member, a valve seat and a blocking member. Mantz discloses an apparatus that does provide an inhalation valve that comprises a valve member, a valve seat and a blocking member (**see figure 5A and 5B**) providing means to prevent deformation and inversion thereby maintaining the proper flow of respiratory gases. Therefore it would have been obvious to modify Farmer's invention by providing an inhalation valve that comprises a valve member, a valve seat and a blocking member as taught by Mantz doing so would have provided a valve means to prevent the deformation and inversion thereby maintaining the proper flow of respiratory gases (**see abstract**).

21. **As to claim 6**, Mantz teaches a valve member that is a center post valve member connected to the valve seat (**see figures 5A and 5B**).

22. **As to claim 7**, Mantz teaches a blocking member that has at least one opening formed therein to permit the flow of gases therethrough (**see figures 5A and 5B**).

23. **Claims 8 and 28** is rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer (US 20020069870) in view of Richardson et al. (US 6,279,574).

24. **As to claims 8 and 28**, Farmer discloses the applicant's invention as claimed with the exception of providing an inhalation conduit that comprises an endotracheal tube. Richardson discloses an apparatus that does provide an inhalation conduit that comprises an endotracheal tube as well as a WYE connector, which are well known in the respiratory art. Therefore it



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would have been obvious to modify Farmer's invention by providing an inhalation conduit that comprises an endotracheal tube and a WYE connector as taught by Richardson.

***Allowable Subject Matter***

25. Claims 11-14 are allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nihir Patel  
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*Jana Mitchell*  
Primary Examiner